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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/962,523 10/31/97 FISCHETTI

V NEWH-1

EXAMINER

HM12/0414

JONATHAN E GRANT  
2120 L STREET, N.W.  
SUITE 210  
WASHINGTON DC 20037

ART UNIT	PAPER NUMBER
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9

1615

DATE MAILED:

04/14/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/23/98; 2/26/99 and 3/29/99.

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 26-51 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 26-51 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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### Detailed Action

1. Applicant's election without traverse of claims 1-5 and 23-25 (now claims 26-51) in Paper No. 6 is acknowledged.
2. Claims 26-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "phage associated lysin enzyme" is vague and indefinite in the context employed because the metes and bounds of the patent protection desired are unascertainable. It is the Examiner's position that this term does not meet the threshold requirement of clarity and precision and is not in compliance for definiteness of 35 U.S.C. 112, second paragraph.

3. Claims 26-51 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The recitation in the claims of the pH range of the enzyme ranging from 4.0-8.0 (p. 7) is a feature that is critical or essential to the practice of the invention, but is not included in the claim(s). Hence, the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 U.S.P.Q. 356 (CCPA 1976). Note that the above-mentioned limitation is not a preferred

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embodiment of the present invention but a critical limitation. Claims are read in light of the specification, and the claims in this case are not commensurate in scope with the specification in the absence of this limitation. In other words, the present claims do not "reasonably correlate" with the scope of the specification. Therefore, "undue experimentation" would be required by one of ordinary skill in the art at the time of this invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Raj Bawa, Ph.D., whose telephone number is (703) 308-2423. The examiner can normally be reached on Tuesday through Friday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

BAWA; aco  
April 1, 1999  
April 12, 1999



RAJ BAWA, Ph.D.  
PRIMARY EXAMINER  
GROUP 1600